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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,588	01/16/2001	Melton B. Affrime	AL01132K	4299

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EXAMINER
DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/760,588	AFFRIME ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-20, 22-25, 27-39, 41-46, 48-49, 51-60, 63-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-20,22-25,27-39,41-46,48,49,51-60 and 63-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

The following is responsive to the amendment and terminal disclaimer received Jan. 23, 2004.

Claims 1-15, 21, 26, 40, 47, 50, 61-62 are cancelled. New claims 65-68 are added. Claims 16-20, 22-25, 27-39, 41-46, 48-49, 51-60, 63-68 are currently pending.

All previous claim rejections set forth in paragraphs 1-2 of the office action mailed Sep. 25, 2003 **are withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous double patenting rejection set forth on pages 7-8 of the office action mailed Sep. 25, 2003 **is withdrawn** in view of the terminal disclaimer received Jan. 23, 2004.

Upon further review of the application and claims with a technology specialist, the following new ground(s) of rejection are submitted which address issues raised during the review.

New Ground(s) of Rejection

Claim Rejection(s)—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 16-20, 22-25, 27-39, 41-46, 48-49, 51-60, 63-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kou 6,100,274 in view of Hitzig 5,502,080 and Gray 5,698,558.

Kou discloses a method of treating allergic reactions in a mammal, the method comprising orally administering to the mammal an anti-allergic effective amount (preferred, 5-10 mg/day in single or divided doses) of descarbonylethoxyloratadine, i.e. desloratadine. Kou discloses that desloratadine possesses antihistaminic properties. Please see the abstract; col. 5, lines 43-56; claim 1.

Kou does not specifically disclose treating the claimed allergic disorders such as seasonal and perennial allergic rhinitis and chronic idiopathic urticaria. Yet, the Examiner refers to (1) Hitzig, which teaches that rhinitis and urticaria are known allergic disorders (please see col. 1, lines 32-35) and (2) Gray, which discloses that seasonal and perennial allergic rhinitis are immediate-type allergic diseases (please see col. 2, lines 13-30) and that chronic idiopathic urticaria results from allergic reactions and is IgE antibody mediated, the symptoms of which may respond to treatment with histamine H1 receptor antagonists (please see col. 3, lines 16-27).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the treatment method of Kou to use desloratadine in the treatment of seasonal and perennial rhinitis as well chronic idiopathic urticaria because Kou teaches that desloratadine exhibits antihistaminic properties and one of ordinary skill in the art would reasonably expect desloratadine to be effective in treating rhinitis and urticaria. Such a modification would have been motivated by the reasonable expectation that the antihistaminic/anti-allergic properties of desloratadine would be effective against allergic reactions involved in mammals suffering from rhinitis or urticaria.

Concerning the claimed pharmacokinetic profile, upon further review of the specification and the examples contained therein, it is noted that the claimed method essentially involves the oral administration of desloratadine pharmaceutical products available to the public (please see Study Treatments, starting at page 15). However, from the standpoint of patentability, method claims must rely on the method steps

recited. The Examiner respectfully submits that the method steps recited in the claims of the instant application, as presented, are not patentably distinguished from the prior art. The claimed blood/plasma concentrations of desloratadine are inherent, if not obvious, within the dosages achieved and administered to patients suffering from allergies. In other words, it appears as if Applicant is claiming the pharmacokinetic profile resulting from the administration of the known desloratadine compositions.

Finally, with respect to the treatment occurring for about 10 days or 7 days to about 10 days, since Kou discloses that the dosage regimen will depend upon the severity of the allergic condition as well as the patient being treated (please see col. 5, lines 48-54), it would have been obvious to one of ordinary skill in the art to further modify the treatment method such that desloratadine is administered for an amount of time sufficient to successfully treat the allergic disorder.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 16-20, 22-25, 27-39, 41-46, 48-49, 51-60, 63-68 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 15 of U.S. Patent No. 4,659,716 in view of Hitzig and Gray, supra.

USPN '716 claims a method for treating allergic reactions in a mammal, which comprises administering to the mammal an anti-allergic effective amount of the compound in claim 3, i.e. desloratadine.

USPN '716 does not specifically claim treating the claimed allergic disorders such as seasonal and perennial allergic rhinitis and chronic idiopathic urticaria. Yet, the Examiner refers to (1) Hitzig, which teaches that rhinitis and urticaria are known allergic disorders (please see col. 1, lines 32-35) and (2) Gray, which discloses that seasonal and perennial allergic rhinitis is an immediate-type allergic disease (please see col. 2, lines 13-30) and that chronic idiopathic urticaria results from allergic reactions and is IgE antibody mediated, the symptoms of which may respond to treatment with histamine H1 receptor antagonists (please see col. 3, lines 16-27).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the claimed allergy treatment method of USPN '716 to administer desloratadine for the treatment of seasonal and perennial rhinitis as well chronic idiopathic urticaria because one of ordinary skill in the art would reasonably expect the anti-allergic properties of desloratadine to be effective against allergic reactions such as rhinitis and urticaria.

In addressing the claimed pharmacokinetic profile, the claimed blood/plasma concentrations of desloratadine are inherent, if not obvious, within the dosages achieved and administered to the mammals suffering from the allergies.

Conclusion

Claims 16-20, 22-25, 27-39, 41-46, 48-49, 51-60, 63-68 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM
Sept. 22, 2004

Cybille Delacroix-Muirheid
Patent Examiner Group 1600